EXHIBIT 516.1

Curriculum Vitae

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Education

B.S. Pharmacy - Rutgers University, New Brunswick, NJ (1974)
M.S. Pharmaceutical Science - Rutgers University, New Brunswick, NJ (1980)
Ph.D. Pharmaceutical Science - Rutgers University, New Brunswick, NJ (1987)

Summary of Work Experience

Positions held demonstrate growth with an increasing sphere of responsibility as well as the technical ability to manage large groups of colleagues and projects on a global scale. The areas covered in these positions have included production troubleshooting, dosage form development, scale up, technology transfer and project management.

Additional experience was gained at a soft gelatin capsule contract manufacturer. In this position, progress began as Project Manager developing to Area Manager within the manufacturing section.

As president of SommaTech, LLC, my focus is on helping our clients achieve their FDA regulated product goals for a fast submission, seamless approval as well as assuring a cost effective product and a secure supply chain. One client with whom we worked for two years achieved their novel therapeutic product development and commercialization goals. That company was recently acquired for $255 MM, culminating the development and License Agreement and the deferred Merger Agreement.

Areas of Interest

- Technical interest is focused on solid dosage forms and the physical pharmacy surrounding them.
- Managed and enjoyed the diversity of situations presented while fulfilling role as Technical Project Leader on globally positioned projects.
- Within the cross-functional team environment mentored colleagues while providing necessary input as well as insight into a variety of product development efforts within several technical areas.
- Invited as an FDA investigator trainer on numerous occasions. Interwoven in my career path has been continual interaction with the Regulatory Affairs group. This experience led to rare opportunities to use my technical background and presentation skills and supply training on modified release dosage forms and unit operations to the FDA.
- Further extension of my background and relationship with the FDA was the chairmanship of ISPE's SUPAC Equipment Guides committee. This project presented me with several personal challenges including managing a large diverse group of highly experienced scientists and engineers. The effort utilized a staff of 60 professionals. Results were two equipment guidance documents, which are the basis of the FDA's evaluation of comparability of process equipment.

Industry Experience

Novartis (12/75 to 6/04)

Director and Technical Project Leader (2001 – 2004)

Responsibilities: Led three multi-functional teams with the technical responsibility for two novel oral solid dosage delivery systems, as well as providing life cycle management support to maintain growth of a large cardiovascular franchise. The external budget for these projects was over 12 million dollars. An additional challenge was management of unique development needs of an anti-viral compound which represented an entry into a new therapeutic area.

- Novel solid oral delivery system was approved by the FDA during June 2001 with a line extension approval expected April 2004. The product has also been approved in 13 Rest of World countries.
- A fixed combination product has been approved by the FDA contributing to the life cycle of the cardiovascular product.
- A pediatric extension strategy has been implemented for application in support of the anti-viral product as well as in support of the cardiovascular.

Assistant Director, Process Development (1997-2001)
Responsibilities: Led a strong experienced senior staff of 18 professionals having international responsibility for scale-up, technology transfer, and Technical Life Cycle Management. Assigned tasks also included site shut-down and liquidation of 6 million dollars in capital assets in preparation for consolidation to East Hanover. Within the group implemented the Novartis development structure that included a matrix management approach.

- Projects included 4 NCEs in late phase development that were targeted for process introduction at offshore locations. These sites included third-party contractors as well as Novartis assets within the EU.
- Led a multi-functional team with technical responsibility for a novel solid oral delivery system. The product was planned for global marketing position. External budget is 18 million dollars for contractor services through launch.
- Implemented SUPAC IR/MR equipment guidance with society associates and colleagues within FDA/CDER.

Assistant Director and Global Competence FD (1995 – 1996)
Responsibilities: Led a staff of 11 professionals and oversaw Summit, Suffern and Puerto Rico product support and all Late Phase development activities. Assigned leadership role of Global Competence Full Development activities within Pharmaceutical Development worldwide. Implemented new product introduction and launch procedures.

- Oversaw site introductions at three off-shore locations for new compounds and line extensions (life cycle management).
- Worked closely with production operations on a global scale to assure technology and site match for process start up. The dosage forms introduced during this period included inhalation and liquids as well as several novel solid dosage forms.

Manager Solid Dosage Forms, FD (12/91-12/94)
Responsibilities: Headed a staff of 11 professionals and oversaw Summit, Suffern, and Puerto Rico product support and pilot plant operations.

- Initiated international efforts to address emerging validation needs. Presented proposals at several workshops held in the UK using applied experience gained during previously “globalized” product launches. Assumed leadership role as architect of the new technology transfer approach.
- Structure of the department was modified by development phase, EC, ED and FD.
- Submitted capital requests and obtained approval for renovation and construction of the new development facility.
- Represented the department within the therapeutic area project teams for introduction of three additional NCEs.
- Introduced a major NSAID into Puerto Rio with subsequent approval and launch.
- On a personal note fulfilled several high profile humanitarian roles assigned by the Pharma Division President for supply of a discontinued product. Interacted with a politically active and antagonistic individual to satisfy needs for her terminally ill son.

Senior Staff Scientist (7/88 – 12/90)
Responsibilities: Headed staff of 7 professionals with multi-site responsibility.

- Developed line extensions for anti-epileptic product family as well as explored alternative drug delivery technologies.
- Developed an MR version for a major NSAID to provide a line extension, using a conventional matrix technology. This was the first in a series of globalized efforts led using European assets to supply the US market for solid dosage forms.
- Became part of a select team to locate and identify a facility in Puerto Rico to manufacture several high volume products.

Senior Research Scientist (1/84-7/88)
- Reformulation of several organic-based coating processes through the portfolio.
- Established two-site capability for support of a major NSAID introduction.
- Chaired the raw material evaluation group which is a cross functional team.
- Completed development and introduction of a major cardiovascular product. This represented the division's first major PAI that ended successfully with product launch.

Research Scientist (1/82-12/83)
- Installed and qualified the equipment required during manufacture novel drug delivery systems in a solvent environment.
- The Modified Release capability provided by this technology formed the Life Cycle Management strategy for the company going forward.

Scientist I and II (12/75 – 12/81)
- During a 6 month assignment in Basel undertook data collection and development of new coating technology that included osmotic membranes as well as aqueous based films for transfer to the US development center.
- Initiated capital requests to upgrade current coating pilot plant using technology assembled in Basle.
- Transferred numerous products from Summit to Suffern production to ease capacity constraints as well as to begin the consolidation of all operations at the Suffern site.

Chase Chemical
Production Manager- Gelatin and Fill Mfg (6/75-12/75)
- Supervised 35 union personnel involved in gelatin and fill preparation to support a 24-hour soft gel encapsulation process.
- Reduced wastage by supervising gelatin recycling efforts and salvage.

Project Manager (6/74 – 6/75)
- Provided ongoing process improvements for soft gelatin capsules
- Provided production support and troubleshooting
- Completed design and installation of a new capsule washing and pre-drying technology increasing productivity and product quality.

Professional and Honorary Societies
- International Society of Pharmaceutical Engineers (ISPE)
- Drug Product Technical Committee, 2001-present
- Member, *Journal of Pharmaceutical Innovation* Editorial Advisory Board
- ISPE Product Quality Lifecycle Implementation Project for QbD, this committee has been charged with putting in place a body of knowledge for industry use in the preparation of Quality by Design regulatory submissions, Past Chair
- ISPE Professional Certification Commission (CPIP), which is charged with establishing a credential for pharmaceutical industry professionals on a global basis, Past Chair
- ISPE Product Quality Lifecycle Implementation (PQLI), Past Chair
- ISPE Education Committee Chairman 1998-2000
- ISPE/FDA Joint SUPAC Equipment Comparability Steering Committee, Chairman 1996-1998
- Eastern Pharmaceutical Technology Meeting
- General Chairman 1988
- Planning Committee 1979-1987
- American Pharmaceutical Association
- New Jersey Pharmaceutical Association for Science & Technology
- Rho Chi Society

Recognition Awards

- Named to “Who’s Who in Science & Engineering"
- Letter of commendation for efforts surrounding the SUPAC equipment list, sent by Susan M Setterberg, Mid-Atlantic Region, US Food and Drug Administration, dated April 7, 1997
- “Hammer Award,” presented by Vice President Gore’s Committee for National Performance Review (NPR). This award is presented to federal employees and their partners who advance the National Performance Review goals of reducing red tape and improving customer service. The award was based on the work conducted in the development, completion and implementation of the “similar equipment” list which was required for CDER’s Scale-Up and Post Approval Change (SUPAC) initiative for immediate release solid oral dosage forms. “Pharm. Eng. 18 (1) 46-58 (1998)”
- “Special Recognition Award”, presented by the Center for Drug Evaluation and Research (CDER), Director Janet Woodcock, MD for invaluable service to the American public by providing technical support to the US Food and Drug Administration in the development of the SUPAC-IR Equipment Guidance “I*speak* 18 (1) 1-2 (1998)
- 2007 Recipient of ISPE’s prestigious Max Seales Yonker Member of the Year Award

Publications and Presentations

R.Somma, "Corrective and Preventive Action-Industry Perspective (Root Cause Analysis: What is the Apparent vs. the True Cause for CAPA)”, ISPE Washington Conference 2010, Washington, D.C., June 7-8, 2010

R.Somma, “Technology Transfer: Materials, process, scale-up, trouble shooting, SUPAC and PAT related issues”, PTI 7th Annual Nassau Inn Meeting: Formulation & Process Development for Oral Dosage Forms, Princeton, NJ, August 29-September 3, 2010

R.Somma, LIVE Podcast: “Tech Transfer: Do We Have a Failure to Communicate?”, January 27, 2010

R.Somma, Podcast: “Tech Transfer” Russ Somma, PhD, 2010, PharmQbD.com and PharmaceuticalManufacturing.com, January 8, 2010

R.Somma, “Building Better Partnerships by Leveraging QbD”, PharmaManufacturing.com, July 22, 2009.

R.Somma, Podcast: QbD’s Future: It’s Here, If You Know Where to Look”, www.PharmaQbD.com, 2009

R.Somma, “What QbD Means in a Contracting Context”, On-Demand Webcast: Pharmaceutical Outsourcing/Pharma QbD, Operational Excellence for Building Better Partnerships, May 14, 2009.

R.Somma, “Formulation & Process Development for Oral Solid Dosage Forms,”, PTI Sixth Annual Training Program, Nassau Meeting, Princeton, NJ, April 30, 2009.

R.Somma, “Up in the Air”, Pharmaceutical Executive, January 1, 2009.

R.Somma, “Competing in the Global Market Place”, 2008 ISPE Annual Meeting, Boca Raton, FL, October 27, 2008.

R.Somma, “Embracing Quality by Design: Applying QbD concepts can help CMOs create value”, Contract Pharma, October 2008.

R.Somma, "Quality by Design: ICH Q8, Q9 and Q10”, Regulatory Affairs Professionals Society's (RAPS) Annual Conference, Boston, MA, September 16, 2008.

R.Somma, “How Quality by Design is Changing Drug Development”, pharmaQbD.com, August 2008

R.Somma, “No More Approvable Letters: An Expert’s Take”, PharmExecBlog, July 16, 2008.

R.Somma, “New Aspects of Quality by Design”, PTI Fourth Annual Training Program on Advances in Tabletting Technology: New Technologies, Trouble-Shooting, SUPAC and PAT Related Issues, Princeton, NJ, May 1, 2008.

R.Somma, Expert Briefing Webinar “Using Quality by Design (QbD) in Designing Efficient, FDA Compliant Pharmaceutical Manufacturing Processes and Facilities”, April 23, 2008.

R.Somma, “Wyeth Gets Exclusive License for Mochida’s Painkiller Drug”, PharmAsia News, January, 2008.

R.Somma, “Development Knowledge Can Increase Manufacturing Capability and Facilitate Quality by Design” J.Pharm. Innov. 2, 87-92 (December 2007).

R.Somma, “FDA’s Approvable Problem”, Pharmaceutical Executive, November 2007.

R.Somma, “Basic Principles of Solid Dosage Formulation & Process Development”, In-House Training Program at Merck & Co, West Point, PA, October 10 -11, 2007.

R.Somma, “Using Technology Transfer to Maximize Business Efficiency”, Pharm. Eng. 27,5 (September/October 2007).

R.Somma, Webinar: "Business Solutions for Understanding and Implementing the New FDA GMP's for Nutritional Supplement Manufacturing”, Contract Pharma, September 25, 2007.

R.Somma, “Road Map to Successful Pat Applications", Rutgers University, Industrial Engineering Department, PAT Conference, Las Vegas, Nevada, June 18, 2007.

R.Somma, “Quality by Design Impact on Operations”, Facilities Summit, ISPE Washington Conference, June 4, 2007.

R.Somma, ISPE Workshop with FDA participation to discuss the issues and gain industry input on the implementation of new quality guidelines (Q8 and Q9) developed by ICH, Alexandria, VA, June 4 - 7, 2007.

R.Somma, “Product Quality Lifecycle Implementation, The Road Ahead for QbD”, ISPE Washington Conference, June 6, 2007.

R.Somma, “Aspects of Non-Invasive Drug Therapy- a Technology View Point”, Life Science and Technology, Third Quarter 2007.

R.Somma, PTI 4th Annual Nassau Inn Meeting, “Formulation & Process Development For Oral Dosage Forms”, Princeton, NJ, April 22 - 27, 2007.

R.Somma, "Technology Transfer or Knowledge Transfer for Solid Oral Dosage Forms", ISPE NJ Chapter Holiday Inn Raritan, NJ, November 16, 2006.

R.Somma, Certified Pharmaceutical Industry Professional (CPIP), Workshop. ISPE Annual Meeting Orlando, FL, November 5-8, 2006.

R.Somma, "Engineering A Pharmaceutical Product Using Drug Development Knowledge", Tablets and Capsules Expo, Raritan, NJ, October 9-11, 2006.

R.Somma, “Engineering A Pharmaceutical Product Using Drug Development Knowledge”, ASME Conference, September 2006.

R.Somma, “Using Development Knowledge to Enhance Manufacturing Capability For Novel Dosage Forms”, ISPE Washington Conference, June 6, 2006.

R.Somma, “Using Development Knowledge To Manage Facility and Capacity Needs”, Center for Business Intelligence, Philadelphia, PA, May 22, 2006.

R.Somma, Strategic Facility Planning for Pharmaceutical and Biotech Companies, May 2006.

R.Somma, SUPAC and PAT Related Issues, "FDA's Fast Track Approval or Is It Quality by Design?" Princeton, NJ, April 28, 2006.

R.Somma, PTI, Third Annual Training Program on Advances in Tableting Technology: New Technologies, Trouble-Shooting, SUPAC and PAT Related Issues, “Technology Transfer or Knowledge Transfer for Products and Processes: Which Expedites the Process Most?” Princeton, NJ, April 27, 2006.

R.Somma, 3rd Annual Meeting on Formulation & Process Development for Oral Dosage Forms, March 2006.

R.Somma, “Technology Transfer or Knowledge Transfer of Product Formulations and Manufacturing Processes: Which Expedites the Process More?” Interphex, San Juan, Puerto Rico, February 17, 2006.

R.Somma, “Integrating Technology Transfer with Knowledge Transfer to Expedite the Process”, Technology Transfer for the Pharmaceutical and Biotech Development Lifecycle, Lake Buena Vista, Florida, December 6, 2005.

R.Somma, “FDA’s Fast Track Approval or Is It Quality by Design?” ISPE Annual Meeting, November 7, 2005.

AAPS Northeast Regional Discussion Group, Eight Annual Meeting, “Using IVIVC Predictions to Effectively Manage Process Design,” April 22, 2005.

PTI, Second Annual Training Program on Formulation and Process Development for Oral Solid Dosage Forms,“ Technology Transfer or Knowledge Transfer for Products and Processes: Which Expedites the Process Most?” April 27, 2005.

L. Lee, R. Somma, et al.,” In vitro dissolution and in vivo oral absorption of methylphenidate from a bimodal release formulation in healthy volunteers,” Biopharmaceutics and Drug Disposition, (25) 2,91 (2004).

FDA’s Pharmaceutical cGMPs and Process Analytical Technology (PAT) Symposium, “Current Industry Practices in Manufacturing Process Validation,” June 2, 2003.

“Technology Transfer or Knowledge Transfer For Products and Processes: Which Expedites the Process Most?” NJ Discussion Group, March 1999 PHARMA Meeting, Orlando, FL, April 1999, POWREX Symposium, Osaka, Japan, July 2000.

"Aspects of Technology Transfer," Human Science Project-International Meeting, The National Institute of Public Health, Fujisawa Pharm. Co., Osaka, Japan, July 2000.

New Jersey Pharmaceutical Association for Science and Technology, Spring Workshop April 27, 2000, R. Somma, Key Note Speaker "Life Cycle Management-The Way of the Future?"

FDA/ISPE, SUPAC Equipment Guides, Conference Leader for the roll out of the Modified Release (MR) Immediate Release (IR) and Semi Solids (SS) Equipment Guidance Documents, Indianapolis 10/96, Tampa 2/97 and 2/98 Philadelphia 4/97, Santa Clara 9/97

J.Bara and R.Somma "Influence of the Physicochemical Variability of Magnesium Stearate on Its Lubricant Properties: Possible Solutions," Drug Dev. And Ind. Pharmacy, 22 (11), 1105 (1996)

FDA Field Investigator Training Program "Time Release Technology, Matrix Tablets" (1991, 1992, 1994, 1995, 1996)

36th Annual Conference on Pharmaceutical Analysis (Land of Lakes Conference) 1996 "Characterization of Key Excepients", R. Somma, July 23, 1996, Merrimac, Wisconsin, January 1997, San Juan, Puerto Rico

AAPS 1995 "The Science of Technology Transfer: The Research and Development Perspective," November 7, 1995, AAPS Annual Meeting Miami Beach, FL.

Rutgers University Centennial Pharmaceutics Conference, "Matrix Tablets," Piscataway, NJ (1992)

EPTM 1990 "Technology Transfer, the International Experience," October 12, 1990, Eastern Pharmaceutical Technology Meeting, Whippany, NJ.

Arden House 1989, "Solids Unit Processes: Theory, Practice and Optimization, Case Studies in Granulation Manufacture."

R. Somma, "Tensile Strength of Fatty Alcohol Sustained Release Matrices as a Function of Heat of Freezing," Pharm. Res., 2 (1987) S-53

R.Somma, "Proceedings of the Sixth Wisconsin Update Conference, Tabletting" (1987) Overview of Tablet Compression Physics, p.7

R.Somma, "Hardness Effects Due To Aging and Dwell Time During Compression of Fatty Alcohol Compacts and Their Excepients" (1987) Rutgers University, Ph.D. Thesis